

United States District Court
Northern District of California

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,
Plaintiff,
v.
ELIZABETH A. HOLMES,
Defendant.

Case No. [5:18-cr-00258-EJD-1](#)

ORDER RE PRE-TRIAL MOTIONS

Re: Dkt. Nos. 892, 895, 897, 899

On July 28, 2020, a federal grand jury returned a Third Superseding Indictment, charging Defendants Elizabeth Holmes and Ramesh “Sunny” Balwani with ten counts of wire fraud (“Counts 3 through 12”), in violation of 18 U.S.C. § 1343, and two counts of conspiracy to commit wire fraud (“Counts 1 through 2”), in violation of 18 U.S.C. § 1349. Third Superseding Indictment (“TSI”), Dkt. No. 469. Defendants were charged with making deceptive representations about their company, Theranos, and its technology. In anticipation of trial, Holmes and the Government each filed motions in limine (“MIL”), which the Court ruled on. *Mots. in Limine*, Dkt. Nos. 560-578, 588; *Order re: Mots. in Limine (“MIL Order”)*, Dkt. No. 798.

Holmes filed additional pre-trial motions now before the Court. Dkt. Nos. 892, 895, 897, 899. The Court heard oral argument on the motions on August 20, 2021. Dkt. No. 926. Having considered the parties’ arguments, the relevant law, and the record in this case, the Court DENIES and DEFERS the following pre-trial motions, as set forth below.

I. BACKGROUND

The background of the case is set forth in the MIL Order and will not be recited herein. In

1 brief, Holmes is charged with conspiring to commit and committing fraud. Holmes allegedly
 2 made several misrepresentations to investors regarding (1) Theranos’s proprietary analyzer (the
 3 TSPU, Edison, or minilab), (2) approval from government agencies, and (3) Theranos’s financial
 4 condition.

5 **II. LEGAL STANDARD**

6 Motions in limine are a “procedural mechanism to limit in advance testimony or evidence
 7 in a particular area.” *United States v. Heller*, 551 F.3d 1108, 1111 (9th Cir. 2009). Like other
 8 pretrial motions, motions in limine are “useful tools to resolve issues which would otherwise
 9 clutter up the trial.” *City of Pomona v. SQM N. Am. Corp.*, 866 F.3d 1060, 1070 (9th Cir. 2017).
 10 Accordingly, “a ruling on a motion in limine is essentially a preliminary opinion that falls entirely
 11 within the discretion of the district court.” *Id.*; *see Luce v. United States*, 469 U.S. 38, 41 n.4
 12 (1984) (explaining that a court may rule in limine “pursuant to the district court’s inherent
 13 authority to manage the course of trials”).

14 In many instances, however, rulings “should be deferred until trial, so that questions of
 15 foundation, relevancy, and potential prejudice may be resolved in proper context.” *United States*
 16 *v. Pac. Gas & Elec. Co.* (“PG&E”), 178 F. Supp. 3d 927, 941 (N.D. Cal. 2016). For example, in
 17 order to exclude evidence on a motion in limine, “the evidence must be inadmissible on all
 18 potential grounds.” *McConnell v. Wal-Mart Stores, Inc.*, 995 F. Supp. 2d 1164, 1167 (D. Nev.
 19 2014). Thus, denial of a motion in limine to exclude certain evidence does not mean that all
 20 evidence contemplated by the motion will be admitted, only that the court is unable to make a
 21 comprehensive ruling in advance of trial. *Id.* at 1168. Moreover, even if a district court does rule
 22 in limine, the court may “change its ruling at trial because testimony may bring facts to the district
 23 court’s attention that it did not anticipate at the time of its initial ruling.” *City of Pomona*, 866
 24 F.3d at 1070; *see also Ohler v. United States*, 529 U.S. 753, 758 n.3 (2000) (“[I]n limine rulings
 25 are not binding on the trial judge, and the judge may always change his mind during the course of
 26 a trial.”).

1 **III. DISCUSSION**

2 **A. Holmes's Motion to Strike Improper and Untimely Expert Disclosure and to**
 3 **Preclude Expert Opinion Testimony of Dr. Kingshuk Das (Dkt. No. 892)**

4 In November 2019, pursuant to the parties' agreement, the Court entered an order requiring
 5 the Government to serve a summary for each expert witness it intended to call under Federal Rule
 6 of Criminal Procedure 16 by March 6, 2020. Dkt. No. 170 at 13; Dkt. No. 171. At that time, jury
 7 selection was scheduled to begin July 28, 2020 with the first day of trial to take place on August 4,
 8 2020. Dkt. No. 170-6; Dkt. No. 171. The Government served its Rule 16 disclosures on March 6,

9 Jury selection has since been continued to August 31, 2021, owing in part to the ongoing
 10 COVID-19 pandemic. Dkt. No 484; Dkt. No. 650; Dkt. No. 756. In February and June 2021, the
 11 Government interviewed Dr. Kingshuk Das, former lab director of Theranos, and disclosed
 12 interview memoranda for him to Holmes after each interview. Ms. Holmes's Mot. to Strike
 13 Improper and Untimely Expert Disclosure and to Preclude Expert Opinion Testimony of Dr.
 14 Kingshuk Das ("892 Mot."), Dkt. No. 892, at 3; U.S.'s Omnibus Resp. to Def. Holmes' Mots. To
 15 Reconsider or Clarify the Court's Order on Mots. In Limine ("Opp'n"), Dkt. No. 906, at 11. On
 16 July 29, 2021, the Government informed Holmes that it intended to call Dr. Das as a witness in an
 17 email as follows:

18 Further, although we submit it is not necessary, we are
 19 supplementing our Rule 16(a)(1)(G) disclosure to advise you the
 20 government intends to offer testimony from Dr. Kings[h]uk Das. A
 21 summary of his anticipated testimony is set forth in the memoranda
 22 of interview that have previously been produced to you. The bases
 for his opinions, to the extent they constitute expert opinion
 testimony, are set forth in those memoranda of interview,
 THPFM00004005199[1], and the list of documents at ECF 842-1
 pp.10-15.

23 892 Mot. at 2. Holmes now moves to strike the Government's July 29, 2021 supplemental
 24 disclosure and to preclude the Government from eliciting any expert opinion from Dr. Das at trial.
 25 *Id.* at 1.

26 The parties' fundamental disagreement concerns Dr. Das's status as a witness. The
 27 Government asserts that it has always believed Dr. Das to be a percipient witness, that it does not

1 intend to elicit any expert opinion or testimony from him, and that it made its supplemental
2 disclosure out of an abundance of caution once it realized that Holmes perceived him to be an
3 expert witness. Opp’n at 11–16. Holmes argues that Dr. Das’s testimony will be based at last in
4 part on scientific, technical, or other specialized knowledge that renders him an expert witness
5 subject to Rule 16 and Federal Rule of Evidence 702. 892 Mot. at 3–4. In particular, Holmes
6 focuses on Dr. Das’s “Six Sigma” analysis of Edison data and his resulting conclusion that Edison
7 devices did not perform well and did not meet the necessary accuracy and precision requirements.
8 *Id.*

9 At the hearing, the Government provided further clarification on the testimony it intends to
10 elicit from Dr. Das. Based on those representations, the Court is persuaded that Dr. Das may
11 proceed as a percipient witness. However, the parties are on notice that specific details of
12 particular scientific procedures or analyses that would require specialized knowledge to
13 understand and interpret—including the Six Sigma analysis—would move Dr. Das’s testimony
14 from percipient to expert. If expert testimony is introduced, Holmes may object at that time. A
15 *Daubert* hearing will be sufficient to address any prejudice to Holmes, particularly in light of the
16 fact that the parties intend to conduct a *Daubert* hearing mid-trial for the Government’s expert
17 witness, Dr. Stephen Master.

18 Accordingly, the Court DEFERS ruling on Holmes’s motion unless and until Dr. Das
19 offers expert witness testimony at trial.

20 **B. Holmes’s Renewed Motion to Exclude Certain News Articles (Dkt. No. 895)**

21 In her renewed motion, Holmes moves to exclude seven news articles not previously
22 submitted to the Court with her original motion in limine. Ms. Holmes’ Renewed Mot. to Exclude
23 Certain News Articles, Dkt. No 895 (“895 Mot.”). The Government, however, calls the present
24 motion premature and potentially unnecessary given presentation of evidence has not begun, and
25 the Court agrees. Opp’n at 3–4; Aug. 20, 2021 Hr’g Tr. (“8/20/2021 Tr.”), Dkt. No. 939, at 7:21 –
26 8:2, 13:15–14:1.

27 In its opposition and at the August 20, 2021 hearing on this motion, the Government

1 committed to not referencing these articles, or any information contained in them, in its opening
2 statement. Opp'n at 3; 8/20/2021 Tr. at 10:9-21. The Government also maintained it would
3 provide advance notice and lay foundation for admissibility if it subsequently intends to introduce
4 any of the seven articles. *Id.* The Court takes the Government at its word and thus DEFERS
5 ruling on the motion unless and until the Government seeks introduction of any of the seven
6 articles at trial.

7 **C. Holmes's Motion to Partially Redact Government Agency Reports (Dkt. No.
8 897)**

9 In its MIL Order, the Court deferred ruling on Holmes's Motion to Exclude FDA
10 Inspection Evidence. MIL Order at 16. The Court held that "evidence arising out of the FDA
11 inspection" was relevant, more probative than prejudicial, and not excludable under Rule 404(b).
12 *Id.* at 11–13. Regarding the two FDA inspection reports (referred to as Form FDA-483s), the
13 Court held they were admissible under Federal Rule of Evidence 803(8)(A)(ii) because they
14 "consist[] largely of observations" comparable to those made by "government employees such as
15 city building inspectors, medical examiners, and prison case managers." *Id.* at 14 (citing cases).
16 The Court noted that there were portions of the report that go beyond mere observations. The
17 Court expressed its openness to continued discussions regarding the issue should Holmes wish to
18 raise arguments as to certain specific pieces of evidence within the FDA inspection evidence that
19 involve such a high degree of observer analysis that they might not be admissible under Rule
20 803(A)(ii). *Id.*

21 Also, in the MIL Order, the Court denied Holmes's Motion to Exclude Evidence of CMS
22 Survey Findings and granted the Government's corresponding motion to admit the Form CMS-
23 2567. *Id.* at 20. The Court held that "evidence of CMS survey findings and sanctions" was
24 relevant to questions about Holmes's state of mind, intent, and knowledge regarding the alleged
25 misrepresentations about the accuracy and reliability of Theranos' blood tests." *Id.* at 18. The
26 Court rejected Holmes's hearsay argument for the same reasons it rejected the argument as to the
27 FDA inspection reports. *Id.* at 20. The Court, however, acknowledged "the possibility for further

1 side bar discussions on this matter, should [the] parties wish to specify certain exhibits within this
2 collection of evidence and make new arguments as to why these particular exhibits should still be
3 excluded.” *Id.*

4 Without waiving her objections, Holmes moves to redact three of the Government’s
5 exhibits: a Form FDA-483 for Theranos’s Palo Alto facility, a form FDA-483 for the Newark
6 facility, and a Form CMS-2567, as well as the cover letter accompanying the Form CMS-2567.
7 Ms. Holmes’ Mot. to Partially Redact Gov’t Agency Reports (“897 Mot.”), Dkt. No. 896; *see* Decl.
8 of Amy Mason Saharia in Supp. of Ms. Holmes’ Mot. to Partially Redact Gov’t Agency Reports,
9 Dkt. No. 898, Exs. 4-6. Specifically, Holmes proposes redacting (1) what she perceives as high-
10 level subjective conclusions of the reports’ authors such that only the factual observations of the
11 authors will be admitted at trial; (2) purported double-hearsay; and (3) tests not identified in the
12 Bill of Particulars.

13 **1. Form FDA-483 Palo Alto Facility (Exhibit 4)**

14 The Court finds that the proposed redactions to Exhibit 4, Form FDA-483 for the Palo Alto
15 Facility, consist of observations that fall within Rule 803(8)(A)(ii), and therefore are admissible.
16 The Form FDA-483, which was issued to Holmes, recites that “[t]his document lists observations
17 made by the FDA representative(s) during the inspection of your facility”; that they are
18 “inspectional observations” and do not represent a final Agency determination regarding
19 compliance. Dkt. No. 898-4 at 2. Holmes proposes redactions to four sentences summarizing
20 observations regarding lack of documentation. For example, the proposed redaction for
21 “Observation 1” merely summarizes the FDA representative’s observation that the documents
22 reviewed by the representative did not address certain assays and that there was an absence of
23 documentation regarding investigation for other assays. *Id.* Similarly, the proposed redaction for
24 “Observation 2” summarizes the FDA representative’s observation that the design validation plan
25 lacks information such as the TSCD lot numbers used. These sentences do not reflect such a high
26 degree of observer analysis that they fall outside the purview of Rule 803(A)(ii).

27 Accordingly, the Court DENIES Holmes’s motion as to Exhibit 4.

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2. Form FDA-483 Newark Facility (Exhibit 5)

Most of the observations set forth in the Form FDA-483 for the Newark Facility are similar in kind and character to those described above. One exception is the proposed redactions under the “Observation 1” heading. These proposed redactions are provisionally approved because at present, the redacted portions lack foundation. If a proper foundation is laid, the Government may seek reconsideration of the Court’s ruling.

Holmes also requests redaction of the five-step procedure under the “Observation 2” heading, asserting that it is hearsay. The hearsay objection is overruled; the five-step procedure is not an out-of-court statement being offered to prove the truth of the matter asserted.

The Court DENIES Holmes’s motion as to Exhibit 5, except that the Court provisionally approves the proposed redactions under the “Observation 1” heading.

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3. Cover Letter and Form CMS-2567 (Exhibit 6)

Holmes proposes extensive redactions to the cover letter and Form CMS-2567. The Court previously held that both are more probative than prejudicial and not hearsay. MIL Order at 12.¹ The Court agrees with the Government that Holmes’s present motion is essentially a motion for reconsideration for which no new arguments have been presented to justify the breadth of the redactions requested.

Nevertheless, rather than deny the motion outright, the Court DEFERS ruling on the proposed redactions until the Government seeks to introduce the cover letter and Form CMS-2567 at trial. The Government shall provide Holmes and the Court with advance notice of the portions

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¹ The Court rejects Holmes’s assertions that the cover letter is “new” and not covered in the MIL Order. Holmes previously sought to “exclude evidence relating to the findings of surveys of Theranos’ clinical laboratories conducted by the Centers for Medicare & Medicaid Services’ (“CMS”) in 2015 and 2016, including the survey reports and sanctions imposed by CMS.” Dkt. No. 574 at 1. In that motion in limine, Holmes referred to the cover letter and the Form 2567 collectively as the “January 2016 CMS Report.” *Id.* at 3. According to Holmes, in the January 2016 CMS Report, “CMS asserted Theranos’s California lab was in violation of various CLIA requirements and warned that if Theranos did not remediate these deficiencies within 10 days, CMS would impose sanctions.” *Id.* Holmes argued that the “findings that Theranos had violated CLIA regulations are irrelevant.” *Id.* at 3. Therefore, the Court construed Holmes’s motion in limine as seeking exclusion of both the cover letter and the Form 2567.

1 of the cover letter and Form CMS-2567 it intends to offer.

2 **D. Holmes’s Renewed Motion to Exclude Certain Doctor Testimony (Dkt. No.**
3 **899)**

4 Next, Holmes renews her motion to exclude certain doctor testimony. Holmes’s Renewed
5 Mot. to Exclude Certain Doctor Testimony (“899 Mot.”), Dkt. No. 899. Previously, Holmes
6 sought to exclude expert testimony from nine medical professionals whose patients received
7 allegedly inaccurate Theranos tests results during the period of the charged conspiracy. *See*
8 Holmes’s Mot. in Limine to Exclude Expert Opinion Testimony of Fact/Percipient Witnesses
9 Under Rules 401-403 and 702, Dkt. No. 561. Holmes argued in part that for a number of these
10 doctors, the Government had failed to disclose the test results and customers on which their
11 opinions would be based. *Id.* at 10–12. In its ruling on Holmes’s motion, the Court “agree[d]
12 with Holmes that the disclosures [were] lacking in information necessary for her to adequately
13 prepare for trial,” but, based on the Government’s representation that it would provide an updated
14 disclosure, denied the motion to exclude “without prejudice, subject to renewal should the
15 Government fail to provide updated disclosures in advance of trial.” MIL Order at 55–56.

16 Following the Court’s ruling, Holmes met and conferred with the Government regarding a
17 due date for updated disclosures. The parties agreed that the Government would “provide an
18 amended set of disclosures for all physician witnesses” by July 30, 2021. Decl. of Amy Saharia in
19 Supp. of Holmes’s Renewed Mot. to Exclude Expert Testimony, Dkt. No. 900, Ex. B at 1. On
20 July 30, 2021, the Government provided its amended disclosure. *See id.*, Ex. D. The disclosure
21 identified the seven physicians who would testify as well as the number of customers and which
22 assays the physicians would discuss. *Id.*, Ex. D at 2–10. Additionally, the Government stated that
23 its July 30, 2021 disclosure “supersedes” its prior disclosures. *Id.*, Ex. D at 1.

24 Still, Holmes now asks the Court for an order excluding any doctor testimony not disclosed
25 in the Government’s July 30, 2021 amended disclosure. The Court, however, afforded Holmes the
26 opportunity to renew her motion to exclude expert testimony of physician witnesses if the
27 Government failed to provide updated disclosures in advance of trial. Given the Government’s

1 July 30, 2021 amended disclosure, the Court sees no reason to depart from its previous MIL Order
2 and finds that a further order is unnecessary at this time.

3 Accordingly, the Court DENIES Holmes's renewed motion to exclude certain doctor
4 testimony.

5 **IT IS SO ORDERED.**

6 Dated: August 30, 2021



EDWARD J. DAVILA
United States District Judge

United States District Court
Northern District of California

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